K012489

Attachment 4 510 (k) Summary

Sponsor:	Appriva Medical, Inc. 777 North Pastroia Ave. Sunnyvale, CA 94043	
Device Name:	X-Sept Transseptal Sheath and Transition Catheter (with Dilator)	
Contact Person:	Michael Kolber Vice President, Regulatory Affairs and Quality Assurance Telephone: 408.616.5203 Fax: 408.616.5252 Email: mkolber@apprivamed.com	
Trade Name	X-Sept Transseptal Sheath and Transition Catheter	
Common/Classification Name	Catheter Introducer	
Establishment Registration:	2954914	
Address of Manufacturing Facility and Sterilization Site	**Manufacturing Facility** Appriva Medical, 777 North Pastoria Ave Sunnyvale, CA 94043 and/or MedSource Technologies 3310 Montgomery Drive Santa Clara, CA 95054	**Sterilization Site** Centurion Sterilization Services 301 Catrell Drive Howell, MI 48843
Classification	The FDA has classified devices of this type as Class II devices (21CFR 870.1340, Catheter Introducer).	
Reason for Pre-market Notification (Substantial Equivalence)	The intended use for the X-Sept Transseptal Sheath and Transition Catheter (with Dilator) is substantially equivalent to the X-Sept Transseptal Sheath and Transition Catheter marketed by Appriva Medical, Inc. The intended use is also consistent with the identification in 21CFR870.1340, which states that a catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery. The X-Sept Transseptal Sheath and Transition Catheter (with Dilator) is substantially equivalent in materials and design parameters to the Appriva Medical, Inc, X-Sept Transseptal Sheath and Transition Catheter. In instances where technological characteristics are different, it has been demonstrated through biocompatibility and in-vitro (functional) testing that there are no questions raised regarding safety or efficacy of the device.	
Identification of Predicate Device	**Manufacturer and Device Name**	**510(k) Number**
	Appriva Medical, Inc., X-Sept Transseptal Sheath and Transition Catheter (with Dilator)	K002054
Compliance with Performance Standards	None are established under Section 514.	

Signature of Applicant:

Michael Kolber
Vice President, Regulatory Affairs and Quality Assurance

8/16/2001
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Mr. Michael Kolber
Vice President, Regulatory Affairs and Quality Assurance
Appriva Medical, Inc.
777 North Pastroia Ave.
Sunnyvale, CA 94043

Re: K012489
X-Sept Transseptal Sheath and Transition Catheter
Regulation Number: 870.1340
Regulatory Class: II (two)
Product Code: DYB
Dated: August 2, 2001
Received: August 3, 2001

Dear Mr. Kolber:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2 Indications for Use Statement

510(k) Number: ~~K002054~~ K012489

Device Name: X-Sept Transseptal Sheath and Transition Catheter (with Dilator)

Indications for use: The X-Sept Transseptal Sheath and Transition Catheter is indicated for percutaneous introduction of various cardiovascular devices into the left side of the heart through the atrial septum.

Division of Cardiovascular & Respiratory Devices
510(k) Number K012489